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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,719	12/02/2004	Stefano Turchetta	TURCHETTA ET AL 2 PCT	9903
25889	7590	06/14/2007	EXAMINER	
WILLIAM COLLARD COLLARD & ROE, P.C. 1077 NORTHERN BOULEVARD ROSLYN, NY 11576			PESELEV, ELLI	
			ART UNIT	PAPER NUMBER
			1623	
			MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p align="center">10/516,719</p>	<p>Applicant(s)</p> <p align="center">TURCHETTA ET AL.</p>	
	<p>Examiner</p> <p align="center">Elli Peshev</p>	<p>Art Unit</p> <p align="center">1623</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

The abstract of the disclosure is objected to because it has not been presented in the proper domestic form. Correction is required. See MPEP § 608.01(b).

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The structural formula or the full chemical name of iminoether (2) has not been set forth in claim 1.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-8 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Heggie et al (EP 0 879 823 A1).

Heggie et al disclose the claimed process for preparing azithromycin by hydrogenating the iminoether with a noble metal catalyst, such as platinum and hydrogen at a pressure between 20 and 70 bar and temperature between 0 C and 50 C. and methylating the resulting compound in the presence of formaldehyde or a source thereof (column 1, lines 55-59) and column 2). Heggie et al also disclose the addition of an acid, such as acetic acid, in the hydrogenation step (Example 1, column 3). Further, the crystalline azithromycin of claim 14 is anticipated by crystalline azithromycin disclosed by Heggie et al.

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al (U.S. Patent No. 6,268,489) or Aronhime et al (U.S. Patent No. 6,586,576).

Each of Allen et al and Aronhime et al discloses the claimed crystalline azithromycin.

Claims 1-8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heggie et al (EP 0 879 823 A1).

Heggie et al disclose a process for preparing azithromycin comprising hydrogenating the iminoether with Pt/C in the presence of acetic acid and methylating the resulting compound with formaldehyde but do not disclose the hydrogenation step in the presence of phosphoric acid. However, a person having ordinary skill in the art at

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the time the claimed invention was made would have been motivated to substitute one well known acid for another in the convention hydrogenation process because the results obtained from said substitution are to be expected.

Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heggie et al (EP 0 879 823) in combination with Aronhime et al (U.S. Patent 6,586,576) Heggie et al disclose a process for preparing azithromycin as discussed above and recrystallizing said azithromycin by eliminating, adding water and then base and drying the resulting product (Example 1) but do not disclose the addition of an organic miscible solvent and drying in an oven under pressure. However, since Aronhime et al disclose the addition of acetone in the crystallization of azithromycin and drying said product in an oven under pressure (Examples in columns 4-5), a person having ordinary skill in the art at the time the claimed invention was made would have been motivated to crystallize azithromycin prepared by Heggie et al by the process disclosed by Aronhime et al because such a person would have expected to prepare pure azithromycin.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev


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GROUP 1200